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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/171,928	10/05/1998	NORIO INOMATA	47259-0336	8658

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DRINKER BIDDLE & REATH (DC)  
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WASHINGTON, DC 20005-1209

EXAMINER
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BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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02/08/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/171,928

Applicant(s)

INOMATA ET AL.

Examiner

Michael Borin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_\_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10/31/2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 8-11, 21 and 30-35 is/are pending in the application.
- 4a) Of the above claim(s) 8-11 and 30-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 10/31/2007; 12/11/2007.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission of Information Disclosure Statements has been entered.

It is noted that applicant refers to the accompanying Request for Personal Interview; however, no such request has been filed.

### ***Status of claims***

1. There is no change in the status of claims. In response to final Office action of 07/05/2007 applicant filed response of 10/31/2008, request for continuing examination and two information Disclosure Statements.

### ***Information Disclosure Statement***

2. Applicants' Information Disclosure Statements filed on 10/31/2007 and 12/11/2007 have been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

### ***Claim Rejections - 35 U.S.C. § 103.***

3. Claims 33,34 remain rejected under 35 U.S.C. 103(a) as obvious over Blaine in view of Gomez et al and further in view of Baker et al.

The claims are directed to method for decreasing ventricle weight comprising administering a natriuretic peptide. The patients to be treated are suffering from cardiac hypertrophy which produces pulmonary congestion.

Blaine teaches method of treatment of cardiac hypertrophy using atrial natriuretic peptide (ANP) and fragments thereof. See abstract, summary, col. 3, lines 11-20, and claims 1-8. In particular, the treatment reverses cardiac hypertrophy and reduces heart weight – see Example 11, col. 4, lines 23-41. Thus, the reference teaches method of reducing heart weight after cardiac hypertrophy.

Blaine does not specifically states that cardiac disfunction produces pulmonary congestion. However, the Blaine reference is not limited to any particular outcome of cardiac disfunction which involves cardiac hypertrophy; rather, the reference teaches that any disorders of altered vascular resistance and/or of electrolyte disbalance can be treated (col. 3, lines 11-20). Applicant argues that Blaine does not teach treatment of cardiac hypertrophy occurring during such chronic cardiac disfunction which produces pulmonary congestion. However, again, the reference is silent about the nature of cardiac hypertrophy and broadly addresses any cardiac hypertrophy. Thus, the disclosure of Blain would motivate one skilled in the art to use natriuretic peptides to treat any cardiac hypertrophy. As for treating cardiac hypertrophy occurring during “chronic cardiac disfunction which produces pulmonary congestion”, both pulmonary

congestion and cardiac hypertrophy are common signs of heart failure - see Gomez et al for example (p. 804, first line) – so it would be obvious to one skilled in the art that the method of Blaine generally addressing cardiac hypertrophy will be applicable cardiac hypertrophy occurring during “chronic cardiac dysfunction which produces pulmonary congestion” as instantly claimed.

With respect to change in the claim language to address method for decreasing ventricle weight, instead of decreasing heart weight as claimed previously, cardiac hypertrophy is manifested first and foremost in the enlargement of left ventricular – see, for example, Baker et al, abstract. See also demonstration of this effect in Example 2 of the instant specification. Thus, it would be obvious to one skilled in the art that decrease in heart weight demonstrated in Blaine would indicate reduction in ventricular weight.

Finally, with respect to applicant's argument that measurement of water/body weight is distinguishable from measurement of ventricular weight/body weight in the instant case, Examiner disagrees and points out that these are two alternative ways of measuring reduction in heart hypertrophy, and there is no indication in Blaine reference that cardiac hypertrophy being treated therein is any different from cardiac hypertrophy addressed in the instant claims.

#### Response to arguments

With regard to Blaine reference, applicant repeats the argument that measurement of water/body weight in Blaine is distinguishable from measurement of

ventricular weight/body weight in the instant case or in the reference of Baker.

Examiner agrees that these are different assays, but reiterates that these are two alternative ways of measuring reduction in heart hypertrophy, and there is no indication in Blaine reference that cardiac hypertrophy being treated therein is any different from cardiac hypertrophy addressed in the instant claims. If applicant believes that measurement of water/body weight, as in Blaine, had it been used in the instant method would not indicate reduction of ventricular mass, applicant is invited to submit a Declaration to this effect.

With regard to submitted Calderone reference, applicant asserts that the background provided by this article proves that "Blaine does not teach the subject matter of the instant claims". However, applicant seem to be discussing two distinguishable forms of myocardial hypertrophy but does not indicate which one of those (if any) is the objective of either instant method or method of Blaine (both of which are addressing generic, rather than specific, disorders).

With regard to Baker reference, applicant discusses details of the article, such as objective and methods of the Baker's study. However, the reference is used merely to support a well known notion that cardiac hypertrophy is manifested first and foremost in the enlargement of left ventricular. To further demonstrate such causative relation, new references of are now added in the list of prior art of record.

With regard to reference of Gomez, applicant states that the citation to p. 804 is in error. The Gomez reference was used in the rejection merely to reflect that both

pulmonary congestion and cardiac hypertrophy are common signs of heart failure.

Gomez, in paragraph bridging p. 803-804 states that "typical signs of heart failure including cardiac hypertrophy, pulmonary congestion and pleural effusions, ..."

Particular of Gomez study discussed by applicant were not addressed and/or used in the rejection.

For the above reasons applicant's arguments are not deemed to be persuasive, and the rejection is maintained.

4. Claim 35 is rejected under 35 U.S.C. 103(a) as obvious over Blaine in view of Gomez et al and further in view of Baker et al as applied to claims 33,34 above, and further in view of Saito et al (Circulation, 76:, 115-124, 1987).

The references as applied as above. With regard to claim 35, BNP is functional equivalent of ANP – see Saito reference, for example, as discussed in applicant's response of 09/06/2005, p. 6).

***Prior art made of record***

5. The following references are cited to further show the knowledge in the art that cardiac hypertrophy developed by different causes is manifested in ventricular enlargement. See Fulton et al (Br. Heart J.,14(3), 413-420) teaches that ventricular weight is an evidence of cardiac hypertrophy . p. 417-419. Olivetti et al (Cardiovascular Research, 1994, 28(8), 1199-1208) teach that with cardiac hypertrophy ventricular weight is increased. See abstract.

### ***Conclusion***

This is an RCE of applicant's earlier Application No. 09/171928. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Michael Borin, Ph.D.  
Primary Examiner  
Art Unit 1631

mlb